

REMARKS

In the Office Action dated March 6, 2006, claims 1, 2 and 20 are allowable provided that the provisional double patenting issues are resolved. Claims 11, 12, 14-18 and 25-30 would be allowable if rewritten or amended to overcome the rejections under 35 U.S.C. § 112, second paragraph, and the provisional double patenting issues are resolved. Claim 13 is rejected under 35 U.S.C. § 102(a) as being anticipated by Peiris *et al.* (*Lancet* 361:1319-1325, published online April 8, 2003; hereafter "*Peiris*") or Drosten *et al.* (*New England Journal of Medicine* 348:1967-1976, published online April 10, 2003; hereafter "*Drosten*") or Ksiazek *et al.* (*New England Journal of Medicine* 348:1953-1966; hereafter "*Ksiazek*"). Claim 3 is rejected under 35 U.S.C. § 102(e) as being anticipated by McSwiggen *et al.* (WO 2004/092383; hereafter "*McSwiggen*"). Claims 22-24 are rejected under 35 U.S.C. § 102(b) as being anticipated by Fodor *et al.* (U.S. Patent Application Publication No. 2001/0053519; hereafter "*Fodor*"). Claim 21 is rejected under 35 U.S.C. § 103(a) as being unpatentable over *McSwiggen*. Claims 11-19 and 25-30 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claims 1-3 and 11-30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over at least claims 18, 23, 26, 28, 29, 31, 32, 75, 77, 79, 136-139, 146, 158, 159 and 166-170 of Application Serial No. 10/808,121. Claim 13 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over at least claims 29, 31 and 44 of Application Serial No. 10/895064.

Non-elected claims 4-10 are herein cancelled. Claims 3, 11-15, 17, 18 and 21-30 are herein amended. New claims 31 and 32 are herein added. No new matter has been introduced. Claims 1-3 and 11-32 are pending in the case.

Reconsideration of the present application in view of the foregoing amendments and the remarks below is respectfully requested.

Claims Rejection under 35 U.S.C. § 102

(1) Claim 13 is rejected under 35 U.S.C. § 102(a) as being anticipated by *Peiris* or *Drosten* or *Ksiazek*.

Specifically, the Office Action states that, with regard to claim 13, the effective date is 4/23/2003, that partial sequences disclosed earlier “are not representative of the full range of primers deduced from the full genomic sequence” and “[t]herefore, the first adequate written description of the genus is 4/23/2003.”

Applicants respectfully traverse the rejection.

The hSARS virus CCTCC-V200303 was deposited under the Budapest Treaty on April 2, 2003 and was described for the first time in provisional application serial no. 60/459,931 filed April 2, 2003, to which the present application claims priority. The partial sequence of the deposited virus was disclosed in another priority provisional application serial no. 60/460,357 filed April 3, 2003, in which the method for identifying a subject infected with the hSARS virus by PCR assay using the primers (SEQ ID NOS:3 and 4 of the present application) derived from the CCTCC-V200303 virus was described.

At the time of the priority dates, one skilled in the relevant art was well acquainted with the knowledge and skills required for DNA technology, such as techniques for DNA sequencing, PCR assay and designing primers for PCR assay. However, in order to develop a method for identifying a subject infected with the hSARS virus, the virus itself had to be first isolated so that its DNA sequence could be determined and PCR primers prepared. Thus, the isolation of the virus is the essential step to come up with the detection method as claimed in the present claim and, once that step is achieved, determining the DNA sequence is a matter of course for anyone skilled in the art. Indeed, the present inventors were the first to isolate and deposit the hSARS CCTCC-V200303 under the Budapest Treaty and thereafter diligently made

their efforts to reveal the entire sequence of the virus. The present inventors disclosed a partial sequence of the virus and a single pair of primers (SEQ ID NOS:3 and 4) on April 3, 2006, thereby successfully reducing the invention to practice. Thus, in view of the disclosure of the deposit CCTCC-V200303 (on April 2, 2003), the partial sequence of the virus and the pair of the PCR primers (on April 3, 2003), one of skill in the art would recognize that Applicants were in possession of the invention recited in claim 13, which uses primers derived from a nucleotide sequence of CCTCC-V200303 virus.

Accordingly, Applicants believe the written description requirement for claim 13 is met as of April 2, 2003, or at the latest, April 3, 2003, which is earlier than any of the cited references. Therefore, Applicants respectfully request that the rejection of claim 13 under 35 U.S.C. § 102(a) as being anticipated by *Peiris* or *Drosten* or *Ksiazek* be withdrawn.

(2) Claim 3 is rejected under 35 U.S.C. § 102(e) as being anticipated by McSwiggen *et al.* (WO 2004/092383; hereafter "*McSwiggen*").

Claim 3 is herein amended to delete SEQ ID NO:2476. Since SEQ ID NO:2473 is not anticipated by or obvious over *McSwiggen*, the rejection of claim 3, under 35 U.S.C. § 102(e) as being anticipated by *McSwiggen* should be withdrawn.

(3) Claim 22-24 are rejected under 35 U.S.C. § 102(b) as being anticipated by Fodor *et al.* (U.S. Patent Application Publication No. 2005/0053519; hereafter "*Fodor*").

Specifically, the Office Action states that *Fodor* teaches the complete set of 10-mers, which includes the 10- mers of claims 22-24.

Claims 22-24 are herein amended to recite "at least 15 contiguous nucleotides". Support for the amendment can be found, for example, at page 19, lines 19-20 and at page 53, lines 25-31.

New claim 31 is herein added for SEQ ID NO:2476 as a claim comparable to claims 22-24, except that the length of the nucleic acid molecule is "from 25 to 100 nucleotides inclusive." Support can be found, for example, at page 53, lines 25-31 of the present specification. Applicants believe claim 31 is neither anticipated by nor obvious over *McSwiggen*.

Claim Rejection under 35 U.S.C. § 103

Claim 21 is rejected under 35 U.S.C. § 103(a) as being unpatentable over *McSwiggen*.

Specifically, the Office Action states that "since all claim 21 requires is the nucleic acid in a container, and containers are very conventional, . . . it would have been obvious to place any or all of the 3,400 sequences of *McSwiggen* in a container."

Based on the Examiner's suggestion, claim 21 is herein amended to recite that the kit contains a polymerase in addition to the recited nucleic acid molecules.

Accordingly, Applicants respectfully request that the rejection of claim 21 under 35 U.S.C. § 103(a) as being unpatentable over *McSwiggen* be withdrawn.

Since a nucleic acid molecule "consisting essentially of the nucleic acid sequence of SEQ ID NO:2474 or 2475, wherein said nucleic acid molecule is 100 nucleotides or less in length" is not obvious over *McSwiggen*, new claim 32 directed to a kit comprising such nucleic acid molecules in one or more containers is herein added.

Claim Rejection under 35 U.S.C. § 112

Claims 11-19 and 25-30 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Office Action states that the claims lack minimum requirements for method steps, but that claims 11, 12, 14-18 and 25-30 would be allowable if rewritten or

amended to overcome the rejection(s) under 35 U.S.C. § 112, second paragraph, and upon resolution of provisional double patenting issues.

Pursuant to the Examiner's suggestions, claims 11-15, 17, 18 and 25-30 are herein amended to recite additional steps for clarification purposes.

With regard to the issues of provisional double patenting, please see below.

Accordingly, Applicants respectfully request that the rejection of claims 11-19 and 25-30 under 35 U.S.C. § 112, second paragraph, be withdrawn.

Rejection under Provisional Double Patenting

Claims 1-3 and 11-30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18, 23, 26, 28, 29, 31, 32, 75, 77, 79, 136-139, 146, 158, 159 and 166-170 of copending application no. 10/808,121. Claim 13 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over at least claims 29, 31 and 44 of copending application No. 10/895,064.

Applicants submit herewith a Terminal Disclaimer to obviate the rejection.

Accordingly, the provisional rejections of claims 1-3 and 11-30 under judicially created doctrine of obviousness-type double patenting over the claims of applications nos. 10/808,121 and 10/895,064, respectively, should be withdrawn.

Application No.: 10/808,187

Docket No.: V9661.0078

Applicants believe all the claims are now in condition for allowance, an early notification of which is earnestly requested.

No fee is believed to be due for this submission. Should there be any deficiency in fees, please charge such fee(s) to Deposit Account No. 50-2215.

Dated: June 6, 2006

Respectfully submitted,

By 

Charles E. Miller

Registration No.: 24,576

DICKSTEIN SHAPIRO MORIN & OSHINSKY
LLP

1177 Avenue of the Americas
New York, New York 10036-2714
(212) 835-1400
Attorney for Applicants

CEM/IY/mgs

Attachment: Terminal Disclaimer